REMARKS

Claims 20-37 are pending, with Claim 20 withdrawn from consideration. By this Amendment, independent Claim 21 is amended. Reconsideration in view of the above amendments and following remarks is respectfully requested.

Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is captioned, "**Version With Markings To Show Changes Made**."

FORMAL MATTERS

Claims 21-36 stand rejected under 35 U.S.C. §112, first paragraph. This rejection is respectfully traversed for at least the reasons set forth below.

The Examiner asserts that the Specification does not provide support for the requirement that the porous articles have "predetermined" levels of porosity. This assertion is respectfully traversed. In addition to showing that the porosity level is controlled, as agreed to by the Examiner, the Specification, on page 9, last paragraph, discloses that the pore sizes in the formed article can be controlled remarkably uniform to yield a material with a predetermined pore size and level of interconnectivity. The true porosity may range from about 20% to about 95%. Moreover, the Specification at page 8, lines 4-8 discloses that previous studies have shown that one gets different growths at different pore sizes. Thus, the

Examiner's suggestion that the claimed method of making a porous article results in a random level of porosity (*i.e.*, not a predetermined level) is inaccurate.

The Examiner recites *In re Wands* (8 USPQ 2nd 1400 (CAFC 1988)) and asserts that *Wands* is concerned with molecular biology. The Examiner then relies upon *Wands* to challenge the adequacy of the disclosure. Applicants agrees that *Wand* is relevant to molecular biology. However, the claimed invention is not concerned with molecular biology. Instead, it is concerned with making a porous article composed of bonded particles (*i.e.*, a ceramic support for bone cells to grow in). That is, the invention lies in the chemistry of how a support is made. The invention is not the realization that you need a defined level of porosity, cell type, and interconnectivity, all of which have been previously explored (see Takagi, U.S. Patent No. 4,654,314). This invention provides an improved way of producing the support.

The Specification discloses various ways to control pore formation. For example, at page 5, the last paragraph, the Specification discloses that another factor which influences the growth of the foam structure is the period before onset of polymerization. This period can be controlled by the additional levels of the initiator and the catalyst. By controlling these levels as well as the oxygen concentration within the foaming gas, the length of time before polymerization starts can be controlled between an instantaneous polymerization and one which starts after a period, which can be up to twenty minutes or more. The Specification then discloses that this period has a major influence on cell structure where the porous article is to be used as a bone substitute. A skilled artisan does not need guidance as to which initiator and

catalyst to use, as the artisan would work that out according to the available materials. The person of ordinary skill in the art also does not need a table of numbers relating to the initiator, catalyst and oxygen levels, because that person can also realize such levels using routine experimentation. Applicants respectfully submit that *Wand* has no relevance in the claimed context of chemical inventions.

Accordingly, Applicants respectfully submit that the claimed invention is described in the Specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the invention was filed, had possession of the claimed invention. Withdrawal of the rejection of the claims under 35 U.S.C. §112, first paragraph, is respectfully requested.

Claims 21-36 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite. This rejection is respectfully traversed for at least the reasons set forth below.

The Examiner asserts that the claims require formation of a porous article having a predetermined level of porosity, but do not set forth the parameters for achieving the predetermined level of porosity. This assertion is respectfully traversed.

Applicants submit that the Specification and claims set forth the parameters for achieving the predetermined level of porosity. For example, Claim 21 recites adding a surfactant and then introducing small bubbles of oxygen containing gas into the dispersion with agitation to form a foam which is allowed or caused to coalesce, and adjusting the period from the formation of the foam to the start of the polymerization by adding initiator and catalyst

therefor at rates selected to influence the structure of the pores to be present in the porous article. Claim 21 further recites that the porous article has a porosity of between 20% and 95%, and comprises pore walls and struts defining pores of pore sizes in the range of 15 to 150 micrometers.

A skilled artisan understands that the level of porosity of a porous article is influenced by the pore size and interconnectivity of the article. The Specification discloses that the surfactant type and concentration can have a direct influence, not only on the level of porosity within a system, but also the pore size and interconnectivity. The concentration of surfactant can be used to influence the bubble size within a foam and the rate of coalescence, both of which can be used to influence the final pore size.

Another factor which influences the growth of the foam structure, and thus the level of porosity, is the period before the onset of polymerization. This period can be controlled by the additional levels of the initiator and catalyst. By controlling these levels, as well as the oxygen concentration within the foaming gas, the length of time before polymerization starts can be controlled between an instantaneous polymerization and one which starts after a period, which can be up to twenty minutes or more. This period has a major influence on foam cell structure and porosity. See page 5, lines 3-7 and 16-22.

In view of Applicants', a skilled artisan would readily understand that the predetermined level of porosity is between 20% and 95%, and that adding a surfactant, introducing small bubbles of oxygen containing gas, and adding initiator and catalyst to adjust the period before

the onset of polymerization are claimed and disclosed parameters for achieving the predetermined level of porosity. Therefore, the claims particularly point out and distinctly recite the subject matter which Applicants regard as the invention. Accordingly, Claims 21-36 are not indefinite. Withdrawal of the rejection of Claims 21-36 under 35 U.S.C. §112, second paragraph is respectfully requested.

PRIOR ART REJECTIONS

Claims 21-29 and 31-33 stand rejected under 35 U.S.C. §102(b) over Sambrook et al. (WO 93/04013). Claims 21-36 stand rejected under 35 U.S.C. §103(a) over Sambrook et al. These rejections are respectfully traversed for at least the reasons set forth below.

The Examiner asserts that Sambrook discloses or teaches all the limitations of the claims, and that controlling the polymerization rate is disclosed at the bottom of page 11. However, Applicants respectfully submit that Sambrook does not teach the claimed method consisting essentially of the features recited in the claims.

For example, Sambrook does not teach the internal pore structure of the article formed, nor does it teach controlling the rate of polymerization. Example VIII of Sambrook shares the use of a polymerizable monomer system, but there is not control of the onset of polymerization. Example IX of Sambrook teaches that the foam was left for 24 hours at room temperature before being dried at 60°C. When this is done, the solids tend to settle, which affects the interior structure of the finally formed article. The same is true of Example X where the homogenized mix was left to stand for 14 hours before heating. As a result, the product

speculation in absence data

of the examples of Sambrook does not have the required properties for bone cell growth. In contrast, in the present invention, the surfactant is added and then air is introduced to form a foam. Once the foam density is achieved, the initiator and catalyst are injected to start the polymerization. In Example I of the instant application, the period between the achievement of foam density was 1.5 minutes. Once the polymerization is finished, the foam is removed, dried and then machined.

Accordingly, Sambrook cannot anticipate the claims because Claim 21 has a number of features which are not disclosed in Sambrook and Sambrook provides a number of features outside of the scope of Claim 21. Therefore, Sambrook does not disclose nor teach the method consisting essentially of the features recited in independent Claim 21, or of Claims 22 - 36 which depend from Claim 21. Withdrawal of the rejection of the claims is respectfully requested.

The Examiner asserts that Sambrook discloses in column 4, lines 3-15 and 52-67, the addition of an initiator and catalyst for pore formation, and that the period for onset of polymerization is instantaneous after stirring catalyst into the foam for 30 seconds. Applicants have carefully reviewed the Sambrook reference and cannot find the location or the text asserted by the Examiner. Applicants respectfully request the Examiner to clarify the location of Sambrook that discloses that the period for onset of polymerization is instantaneous after stirring catalyst into the foam for 30 seconds.

Claims 34 and 35 stand rejected under 35 U.S.C. §103(a) over Sambrook in view of Takagi et al. (U.S. Patent No. 4,654,314). This rejection is respectfully traversed for at least the reasons set forth below.

The Examiner relies upon Takagi for teaching that artificial parts comprising growth of bone cells in ceramic products is known, and for teaching that the pores of the ceramic products should be between 1 and 600 μm to promote induction of new-born bone and turnover of a bone while keeping a good compatibility with a living body.

Takagi teaches the preparation of a porous ceramic body by a variety of ways.

(a) Column 2, line 46 onwards discloses the addition of bubble albumen into a calcium phosphate compound powder, casting the mixture, hardening the albumen, carbonizing the albumen, removing the carbon deposit and sintering at high temperature.

(b) Column 2, line 62 teaches the steps listed in paragraph (a) and adds organic fiber.

(c) Column 3, line 12 teaches mixing a particulate sublimable solid with calcium phosphate compound, press shaping the mixture, heating to remove solid by sublimation, and then sintering.

(d) Column 3, line 24 discloses the steps of paragraph (c) and adds organic fiber.

(e) Column 3, line 41 discloses mixing organic synthetic resin particles to a calcium phosphate compound, press shaping, heating to remove particles by thermal decomposition, and sintering.

(f) Column 3, line 53 discloses the steps outlined in paragraph (e) and adds organic fiber.

(g) Column 4, line 1 discloses the steps outlined in paragraphs (c) and (e) combined.

(h) Column 4, line 17 discloses the steps outlined above in paragraphs (c) and (e) combined, and adds organic fiber.

At Column 1, line 10, Takagi discloses that the resin prepared by the steps outlined in paragraph (e) may be polyethacrylate, polypropylene or polystyrene. These resins are not polymerisable monomers as disclosed in Applicants' invention, instead they are formed polymers.

Moreover, Takagi does not teach the use of polymerisable monomers, affecting the structure of the pores by the control of polymerization (which Takagi could not teach as Takagi does not teach polymerization, and undersintering to achieve a porous body having the defined pore walls and struts), as recited and disclosed in the claims and Specification. Therefore, there would be no incentive or motivation to combine Sambrook and Takagi because they approach the method in two different ways. There is no teaching in Takagi that mix up the deficiencies in Sambrook. Accordingly, Claims 34 and 35 which depend from independent Claim 21 are

not rendered obvious by the combination of Sambrook and Takagi. Withdrawal of the rejection of Claims 34 and 35 under 35 U.S.C. §103(a) is respectfully requested.

Claims 21-36 stand rejected under 35 U.S.C. §103(a) over Sambrook in combination with Hawley's Condensed Chemical Dictionary (1971) and further in combination with Takagi et al. This rejection is respectfully traversed for at least the reasons set forth below.

The Examiner admits that Sambrook and Takagi do not teach that the energy required for reduction in particle size of a solid is directly proportional to the increase in surface area, and relies upon Hawley's Condensed Chemical Dictionary for teaching Rittinger's law. However, Applicants respectfully submit that Hawley's Condensed Chemical Dictionary does not teach the claimed subject matter missing in Sambrook and Takagi as discussed above. Therefore, Claims 21-36 are believed to be allowable over the combination of Sambrook, Takagi and Hawley's Condensed Chemical Dictionary. Withdrawal of the rejection of Claims 21-36 under 35 U.S.C. §103(a) is respectfully requested.

CONCLUSION

For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable consideration and allowance of the claims are earnestly solicited.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact

Applicant's undersigned attorney at the telephone number listed below to further expedite prosecution of the application.

Please charge or credit our Account No. 03-0075 as necessary to affect entry and/or ensure consideration of this admission

Respectfully submitted,

CAESAR, RIVISE, BERNSTEIN,
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December 19, 2002

By _____

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Attachments:
Version with Markings to Show Changes Made

VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

Claim 21 has been amended as follows:

21. (Amended) A method of making a porous article composed of bonded particles and having a predetermined level of porosity, pore size and interconnectivity, the method [comprising steps] consisting essentially of:

(t) forming a dispersion comprising a liquid carrier, particles to be bonded and a polymerizable monomeric material;

(u) adding a surfactant and then introducing small bubbles of oxygen containing gas into the dispersion with agitation to form a foam which is allowed or caused to coalesce;

c) polymerizing the foamed structure;

d) adjusting the period from the formation of the foam to the start of the polymerization by adding initiator and catalyst therefor at rates selected to influence the structure of the pores to be present in the porous article;

(e) drying the structure to remove the liquid carrier and provide a solid article having pores derived from the bubbles; and

(f) firing the article to a temperature to remove the organic material and to undersinter the formed article and thereby form the porous article which has a porosity of 20% to 95% and comprises pore walls and struts defining pores of

pore sizes in the range of 15 to 150 micrometers and in which bone cells may easily be attached.